

FEB 15 2005

**510(k) Summary for  
N Antisera to Human Immunoglobulins (IgG, IgA, and IgM)**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K042735

**1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Marburg GmbH  
Emil-von-Behring Str. 76  
D-35001  
Marburg, Germany

Contact Information: Dade Behring Inc.  
Glasgow Site  
P.O. Box 6101  
Newark, Delaware 19714  
Attn: Kathleen Dray-Lyons  
Tel: 781-826-4551  
Fax: 781-826-2497

Preparation date: September 30, 2004

- 2. Device Name/ Classification:** N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) Assay  
**Class:** Immunological Test System, Class II,  
21 CFR 866.5510  
**Panel:** Immunology  
**Product Code:** CFN

**3. Identification of the Legally Marketed Device:**

N Antisera to Human Immunoglobulins (IgG, IgA and IgM) – K860894

**4. Device Description:**

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.

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**5. Device Intended Use:**

*In vitro* diagnostic reagents for the quantitative determination of immunoglobulins (IgG, IgA and IgM) in human serum, heparinized and EDTA plasma as well as IgG in human cerebrospinal fluid (CSF) using the BN™ Systems.

**6. Medical device to which equivalence is claimed and comparison information:**

The modified N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) assay is substantially equivalent to the N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) currently marketed (K860894). The modified N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) assay, like the current N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) assay, is intended for the quantitative determination of immunoglobulins (IgG, IgA and IgM) by means of immunonephelometry on the BN™ Systems.

**7. Device Performance Characteristics:**

ASSAY	Serum versus	(n=)	+SLO	Intercept	(95% confidence interval)
<b>IgG</b>	Heparinized	49	0.969	0.155	0.993
	EDTA	20	0.978	-0.102	0.993
<b>IgA</b>	Heparinized	49	1.003	-0.031	0.998
	EDTA	20	0.947	0.014	0.998
<b>IgM</b>	Heparinized	49	0.988	0.001	0.994
	EDTA	20	0.920	0.024	0.994



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

FEB 15 2005

Dade Behring, Inc.  
c/o Ms. Kathleen A Dray-Lyons  
Regulatory Affairs and Compliance Manager  
P.O. Box 6101  
Newark, DE 19714

Re: k042735

Trade/Device Name: N Antisera to Human Immunoglobulins (IgG, IgA and IgM)  
Regulation Number: 21 CFR 866.5510  
Regulation Name: Immunoglobulins A, G, M, D, E Immunological Test Systems  
Regulatory Class: Class II  
Product Code: CFN  
Dated: September 30, 2004  
Received: October 1, 2004

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

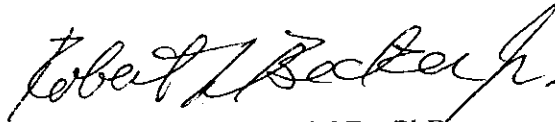
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally

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marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script, reading "Robert L. Becker, Jr.", written in dark ink.

Robert L. Becker, Jr., M.D., PhD

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

## Indications Statement

K042735

**Device Name:** N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) Assay

### Indications for Use:

*In vitro* diagnostic reagents for the quantitative determination of immunoglobulins (IgG, IgA and IgM) in human serum, heparinized and EDTA plasma as well as IgG in human cerebrospinal fluid (CSF) using the BN™ Systems. Measurements of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Prescription Use ☒   
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use \_\_\_\_\_   
(21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chen  
Division Sign-Off

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Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K042735

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